SUMMARY OF
U.S. NUCLEAR REGULATORY COMMISSION / U.S. DEPARTMENT OF ENERGY
QUARTERLY QUALITY ASSURANCE MEETING
JULY 15, 2003

Introduction:

The U.S. Nuclear Regulatory Commission (NRC) and the U.S. Department of Energy (DOE) held a public Quarterly Quality Assurance (QA) Meeting regarding the Yucca Mountain Project (YMP) on July 15, 2003. The meeting was held at the NRC office in Rockville, Maryland, and via video conference to the DOE office in Las Vegas, Nevada, the Center for Nuclear Waste Regulatory Analyses in San Antonio, Texas, and with NRC Region IV in Arlington, Texas. Participants included representatives from the NRC, DOE, Bechtel SAIC Company LLC (BSC), the State of Nevada, Clark County, Government Accounting Office, and members of industry and the public. The meeting agenda and a list of attendees are in Attachments 1 and 2 to this meeting summary, respectively.

Presentations:

DOE personnel made a series of presentations during the course of the QA meeting as described below. A copy of the presentations is in Attachment 3 to this meeting summary.

Dennis Brown (DOE) presented an overview and improvements regarding the DOE QA program. Some of these improvements included: 1) Recent changes to Quality Assurance Requirements and Description (QARD); 2) revision of the review process in procedure AP-5.1.Q, *Plan and Procedure Preparation, Review, and Approval*; and 3) changes made to organization/interface requirements in DOE and BSC.

Mr. Brown discussed DOE's improved corrective action program, which includes simplifying procedure AP-16.4Q, *Corrective Action*, assuring line management accountability, implementation of a new QA trending process; and audit integration between DOE and BSC. Mr. Brown also discussed the software audit and reported that the audit team wrote eight Deficiency Reports (DRs) and concluded that the software process is marginally effective. Thomas Matula (NRC) asked for the definition of "marginally effective" as this term had not been used in the past. Mr. Brown said that "marginally effective" is between effective and ineffective. Mr. Matula also asked how the audit team could conclude that the software process is marginally effective when three critical elements of the software life cycle process (software design, implementation, and testing) were found to be either not effective or indeterminate. Mr. Brown said that the areas evaluated are equally weighted, and that many of the other areas evaluated were found to be acceptable. Mr. Brown indicated that the audit team, which included three nationally recognized software QA experts, determined that the overall conclusion was marginally effective. He also stated that this type of subjective evaluation routinely occurs on all Office of Civilian Radioactive Waste Management audits and throughout the commercial nuclear industry.

Mr. Brown mentioned that Quality Assurance oversight activities since the last QA meeting in April 2003 included, in addition to the software audit, 21 internal surveillances which resulted in issuance of eight DRs; eight external supplier audits which resulted in issuance of 14 DRs; and

Enclosure

integrated internal audits at the U.S. Geological Survey and Los Alamos National Laboratory where no DRs were issued. Further, Mr. Brown discussed the planned integrated internal audits for the fourth quarter of FY 2003, which includes audits of models, data, and design.

Mr. Brown stated that DOE continues to have Quality Focus meetings for DOE and BSC managers, Monthly Operating Reviews, and management interface meetings to increase line management accountability. Furthermore, Quality Engineering is now fully integrated with line management for more effective corrective action resolution.

Lastly, Mr. Brown briefly discussed several noteworthy accomplishments including: 1) The closure of the CAR regarding electronic media storage; 2) audit integration; 3) the software QA audit; and 4) the QARD, Revision 14, approach. Mr. Matula asked about the status of an Audit Observation Inquiry (AOI) written by the NRC Observers during the recent software audit. Specifically, DOE and BSC had written more than 40 DRs regarding software over the past several years. In addition, DOE initiated eight new DRs during a recent software audit. Mr. Matula inquired if DOE will review the previously issued DRs, as well as the eight DRs from the software audit, for possible adverse trends such as ineffective corrective action. Mr. Brown said that DOE does not plan to review the DRs for corrective action effectiveness because the DOE already knows that they have problems with ineffective corrective action, and that the overall corrective actions identified in the Management Improvement Initiatives (MII) will address this issue. Robert Latta (NRC) clarified that the corrective actions in the MII address process issues and do not address ineffective corrective action. Mr. Brown stated that the MII corrective action element is that DOE will develop a single, improved corrective action system. This includes all elements of an effective corrective action system. Mr. Matula pointed out that the QARD requires that DOE evaluate DRs to identify trends, and that DOE should not be selective on which DRs will or will not be evaluated. Mr. Latta stated that the Project's corrective actions have focused on process improvements, not on human performance issues. Therefore, an evaluation of the DRs would evaluate the effectiveness of corrective actions. Mr. Brown said that a response to NRC's AOI regarding this matter is drafted and will be provided to NRC in the near future.

Larry Campbell (NRC) inquired about a second AOI issued by NRC during the recent software audit. This AOI asked about the apparent QA grading of software into Levels A and B. Mr. Brown said that DOE does not perform QA grading for software and that he will provide a response to the AOI which demonstrates that software is not being graded.

Nancy Williams (BSC) discussed the status of the Model Validation Corrective Action Report (CAR BSC-01-C-001) actions. Ms. Williams discussed the status of Model Validation for License Application (LA). Ms. Williams reported that the 11 actions identified in September 24, 2002, response (as modified by an amended response) are complete. Since the last Quarterly QA meeting in April 2003, BSC completed one action regarding the use of performance indicators to assess the effectiveness of the self-identification process. The performance indicators show that the process of self-identification is effective. Ms. Williams stated that DOE/BSC intends to use the upcoming model surveillance as a final measure of effectiveness of corrective action taken regarding CAR BSC-01-C-001. Mr. Matula suggested that, based on the significance and importance of CAR BSC-01-C-001, it may be appropriate to use the results of the upcoming audit on models, rather than the proposed surveillance, to close out the CAR. Mr. Brown agreed and said that DOE will consider completing the model audit before closing CAR BSC-01-C-001.

Ms. Williams reported that BSC is developing 65 model reports under the revised procedure to support the LA. These model reports include those supporting features, events, and processes screening, and implementation of the criticality methodology. Technical Work Plans for each model report, including model validation criteria corrected as part of CAR BSC-01-C-001, are approved by the Chief Science Officer (CSO). To date, 51 model reports have started through in-process model validation review, the CSO has approved 42 model reports during in-process model validation reviews, and 22 model reports have completed CSO technical reviews. The CSO is identifying issues during the in-process reviews and taking appropriate corrective actions.

Ms. Williams then discussed CAR BSC-01-C-002 regarding software development. Ms. Williams reported that: 1) As of June 26, 2003, 306 codes are qualified for use under previous processes; 2) 74 additional codes are in development or in qualification under processes effective January 13, 2003; and 3) the 306 codes baselined under a process in place prior to January 13, 2003 (legacy code), will undergo a retest consisting of installation and validation tests governed by procedure AP-SI.4Q, *Independent Verification and Validation of Legacy Code*. Ms. Williams stated that the DOE implemented an improved procedure for Independent Verification and Validation of software. Lastly, Ms. Williams stated that the corrective actions for CAR BSC-01-C-002 are scheduled to be completed by September 2003.

Ms. Williams then discussed CAR BSC(B)-03-C-107 regarding management of data and data qualification. In her presentation, Ms. Williams discussed the Data Confirmation Project, the status of the CAR, and data metrics. Regarding the Data Confirmation Project, Ms. Williams explained that BSC developed two separate checklists, one for data compliance issues (Phase I) and one for the technical adequacy of data. A review of the checklists will document lessons learned for improvements in the process. Mr. Matula asked if BSC has a plan and procedure for the data confirmation process. Ms. Williams said that the checklists are very detailed and serve as the controls for the activity. The checklists will be considered a quality record and will be maintained as a permanent part of the document package. Mr. Matula asked about the qualifications for the personnel performing the data confirmation process. Ms. Williams stated that each individual will be qualified in the areas that they review. DOE took an action item in this area and committed to discuss with the NRC, management controls surrounding the data confirmation process before or during the next Quarterly QA Meeting.

Regarding the status of CAR BSC(B)-03-C-107, Ms. Williams stated that BSC found ineffective corrective action regarding the management of data and that the root cause determination is in process. The Data Confirmation Project provides the necessary remedial actions for data in the analyses/model reports that support LA. Also, interim verification of data confirmation activities as they relate to CAR BSC(B)-03-C-107 will be performed by BSC QA. Mr. Latta inquired why it is taking so long to complete the root cause determination since the CAR was issued on March 28, 2003. Ms. Williams responded by saying that various members of the root cause team were changed on three separate occasions because of other priorities which resulted in the delays. The root cause determination is now scheduled to be completed in August 2003. Mr. Matula stated that the root cause determination for a CAR of this importance should be given higher priority and completed in a timely manner so that appropriate corrective action can be taken promptly.

Regarding data metrics, Ms. Williams reported that, out of the approximately 120 analyses/model reports and technical reports that support LA, 51 products completed Phase I confirmation and 4 products completed Phase II. Ms. Williams stated that the data confirmation, qualification, and verification are resource intensive because there are an estimated 1,385 data sets that support LA products, of which only 680 data sets are fully qualified and verified.

Mr. Brown then stated that for the next item on the agenda, CAR BSC(B)-02-C-129, regarding the storage of QA data on electronic media, there would be no formal presentation. However, Mr. Brown said that he would take any questions. Mr. Matula asked on what basis did BSC close the CAR. Mr. Brown discussed the results of the DOE Office of Quality Assurance (OQA) investigation requested by the NRC into the closure of the CAR. The NRC had requested that OQA investigate if there was management schedule pressure applied to the BSC Quality Assurance Representative (QAR) to close the CAR prematurely, and if the CAR was verified by the QAR satisfactorily. Mr. Brown read excerpts from the OQA report indicating that the OQA Quality Engineer that performed the investigation, two Navarro QA assessment personnel that observed several BSC surveillances, and two BSC QA personnel involved in the oversight activities all concurred that the activities required to close the CAR were adequate. Mr. Mason said that BSC performed surveillances of the contractor and found their data migration processes to be acceptable. BSC will perform additional surveillances of the contractor to assure continued acceptable performance. Mr. Brown added that BSC is performing a 100% inspection of all migrated data upon receipt in accordance with a recently developed procedure for this inspection. Mr. Matula asked how BSC will inspect the Compact Disks containing the migrated data to assure that all of the data is present and readable. Mr. Brown said that they will provide the information at the next quarterly QA meeting.

Michael Mason (BSC) discussed CAR BSC(O)-03-C-097 regarding procedure development. Regarding its status, Mr. Mason reported that BSC provided the CAR response to DOE, along with the Root Cause Report, on July 3, 2003. In reviewing BSC's CAR response and Root Cause Report, DOE identified 11 comments on the CAR response and 21 comments requiring clarification to the Root Cause Report. Mr. Mason reported that BSC provided its responses to DOE's issues on July 7, 2003. Some of the corrective actions that are being taken include streamlining procedure AP-5.1Q, *Plan and Procedure Preparation, Review, and Approval*, and placing more responsibility on line management; holding Quality Focus meetings to emphasize the importance of procedure compliance; and assigning subject matter experts to each procedure. Mr. Matula inquired about the status of procedure AP-5.1Q. Mr. Mason stated that the procedure will be effective July 18, 2003, and the associated Stop Work Order will be lifted after the CAR response is accepted by DOE OQA. Mr. Matula asked if a root cause determination has been performed on Subpart C of the CAR which identifies that procedure AP-2.14Q, *Review of Technical Products and Data*, does not provide management processes required to address requirements of the QARD. Kerry Grooms (DOE) stated that only one QARD requirement was not covered in the procedure and that this was considered an isolated issue. Therefore, a root cause evaluation is not warranted. Mr. Grooms also stated that the DOE OQA comments made regarding the response and associated root cause did not affect any additional corrective actions or any other root causes. The NRC On-site Representatives will continue to closely monitor the corrective action activities for this CAR.

Mr. Mason then discussed CAR BSC-02-C-001 regarding training and qualification of personnel. Mr. Mason stated that BSC found that the Training Requirements Matrix/Job Function was not updated or provided to Human Resources/Training Organization; there was no record of Verification of Education and Experience (VoEE) available for certain personnel; and training requirements were not identified to subcontractor personnel. BSC has reviewed over 1000 VoEE record packages, is developing a procedure to establish controls for VoEE records, and is developing a single database for BSC and subcontractor personnel to status VoEE.

Mr. Mason finished by discussing design oversight by BSC Quality Engineering (QE) personnel. Mr. Mason discussed the transition of QE personnel from science activities to design activities, how the transition will take place, and the qualifications of current QE staff to be effective in overseeing design activities. Mr. Mason then described the current audit and surveillance schedule for design activities. Mr. Matula stated that the recent data verification and software audits were found to be indeterminate by the NRC observers. Mr. Matula asked if there are any lessons learned from these audits that would assure successful completion of the upcoming model and design audits. Messrs. Brown and Mason said there are lessons learned from these audits that will be utilized in future audits.

Mr. Brown discussed the improvements made to DOE's Corrective Action Program. Mr. Brown described the simplified corrective action process and stated that the status of corrective actions is discussed during Monthly Operating Reviews and weekly Condition Report meetings. QA involvement in the Corrective Action Program includes issuing Condition Reports with no loss of independence, reviewing each Condition Report before issuance, approving corrective action plans, and verifying that corrective actions are completed. Further improvements in the Corrective Action Program include implementing a single entry, software based process that includes automatic notifications and better trending capabilities, screening of issues, guidance on developing corrective actions, guidance on performing root cause analyses, and benchmarking the corrective action program against Institute of Nuclear Power Operations (INPO) and Nuclear Energy Institute (NEI) documents. Mr. Campbell asked if the INPO and NEI documents are used by 10 CFR Part 50 licensees. Rod McCullum (NEI), a meeting attendee, said that these documents are used universally by the nuclear industry. Mr. Brown went on to report improvements in the number of days required to obtain acceptable DR and CAR responses.

Mr. Grooms discussed improvements in DOE's Trending Program. Mr. Grooms stated that the Trending Program is being reviewed as a result of questions raised by DOE management and NRC Onsite Representatives. As a result, DOE has changed cause codes to the DOE Occurrence Reporting and Processing System codes. DOE is now coding Condition Reports from May 2002 and Condition/Issue Identification and Reporting/Resolution System (CIRS) items using the new cause codes. Further changes to the trend program include: 1) preparing improved trend reports; 2) merging Condition Reports, CIRS, Technical Error Reports, and Nonconformance Reports into one system; 3) changing trend reporting to quarterly; and 4) transferring the trend reporting process to BSC. Mr. Matula asked if the new cause codes are comparable to nuclear industry codes. Mr. Grooms said that the new cause codes are comparable to nuclear industry codes and include codes encompassing human performance issues. Mr. Matula suggested that those individuals who are assigning cause codes to human performance issues need to be trained and qualified in that area. Messrs. Grooms and Mason agreed and will assure that only qualified people assign cause codes. Mr. Campbell asked if

the new trending program will have the capability of sorting codes to identify those that pertain to 10 CFR Part 63, *Disposal of High-Level Radioactive Waste in a Geologic Repository at Yucca Mountain Nevada*, issues. Mr. Gooms said that there are additional sorting capabilities available in the program, and additional fields can be added.

Mr. Brown discussed the status of Revision 14 to the QARD. Revision 14 of the QARD will focus on complying with the Yucca Mountain Review Plan (YMRP) and 10 CFR 63. Mr. Brown stated that 24 integrated teams of DOE OQA, DOE line personnel, and contractor personnel are developing positions on the aspects of 10 CFR 63 and the YMRP to assure compliance. Also, OQA is developing crosswalk checklists of YMRP and Part 63 requirements to assure comprehensive coverage in the QARD. Mr. Brown discussed the possibility of conducting either a technical exchange or an Appendix 7 meeting with NRC staff to discuss the proposed changes to the QARD. Mr. Matula indicated that the NRC could support either type of meeting, and that an Appendix 7 meeting might be more appropriate.

Mr. Grooms discussed the integration and coordination of audits between DOE and BSC. Mr. Grooms stated that, before integration of the audits, 20 audits were scheduled for the remainder of FY-2003. After integration, there are 13 audits scheduled for the remainder of FY-2003 because of resource sharing. Audit integration allows for broad QA program coverage with the same resources, minimizing impact to line activities, eliminates redundancy in audit scope and schedule, improves utilization of technical specialists, eliminates need for OQA observers on BSC QA audits, and reduces dependence of BSC QA on BSC Quality Engineering Staff to perform required audits. Mr. Campbell pointed out that DOE is required to evaluate BSC QA activities annually. Mr. Campbell asked if DOE will assure that the independence of auditors will be maintained and assure that DOE auditors have not participated in any activities that they will audit as a result of participating in combined audits with BSC. Mr. Brown said that DOE will use the independent auditors who perform audits of the DOE QA function to evaluate combined DOE OQA and BSC QA audit program activities.

Review of past open action items led to agreement that four of the existing six are closed. Three new action items were identified as indicated in Attachment 4 to this Meeting Summary.

Date

Janet R. Schlueter, Chief
High-Level Waste Branch
Division of Waste Management
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission

R. Dennis Brown 7/24/03 Date

R. Dennis Brown, Director
Office of Quality Assurance
Office of Civilian Radioactive
Waste Management
U.S. Department of Energy

Date 7/23/03

Joseph D. Ziegler, Acting Director
Office of License Application
and Strategy
Office of Repository Development
U.S. Department of Energy